

Question: Why is the National Academies of Sciences (NAS) investigating EPA's research studies?

Answer: The NAS is not investigating EPA research. One of the regulatory requirements for informed consent is to describe "reasonably foreseeable risks" to potential research subjects, and this was one of several topics examined by EPA's Office of Inspector General in their 2014 Report "Improvements to EPA Policies and Guidance Could Enhance Protection of Human Study Subjects." Despite the fact that thousands of research institutions, both inside and outside of government, follow these same regulations, there is no guidance or consensus common practice as to what constitutes "reasonably foreseeable risk," and what information should be included in research the consent forms.

EPA recognized that having subject matter experts provide guidance for our research, and in particular for controlled exposure studies, would further enhance the protections of study subjects at EPA. In 2015, the EPA commissioned the NAS to convene a committee of experts to look at the complicated issues of risk and benefit in our exposure studies. While this was not required, it reflects EPA's commitment to continuous quality improvement and upholding the highest standards in research. The NAS has followed its standard process which is not controlled by the EPA. The NAS report is expected in September-December of 2016; information about the current status of the project is available on the public website of the NAS.

Question: What did the OIG investigate about human subjects research at EPA?

Answer: In response to a congressional request, the OIG conducted a review to determine whether the EPA followed applicable laws, regulations, policies, procedures and guidance when it exposed human subjects to diesel exhaust emissions or concentrated airborne particles in 5 studies that were conducted during 2010 and 2011. The OIG was specifically interested in whether the agency (1) obtained sufficient approval to conduct these studies; (2) obtained adequate informed consent from the human study subjects; and (3) adequately addressed adverse events that occurred during the studies.

Question: What were the OIG's findings?

Answer: On March 31, 2014 the Office of the Inspector General issued a final report reviewing EPA's human studies research program, entitled "Improvements to EPA Policies and Guidance Could Enhance Protection of Human Study Subjects." The findings of the OIG report confirm that EPA followed all laws and regulations concerning human studies-subjects research, and has internal guidelines in place that exceed those normally required by universities, industry and other government agencies conducting human studies research.

Commented [ST1]: Actually, this is correct (albeit counterintuitive). See: <http://www8.nationalacademies.org/cp/projectview.aspx?key=49685>

Commented [ND2R1]: See email. Each academy is still singular.

Commented [ST3]: So I agree that your question is more accurate. But are we trying to come up with the question that people will actually be thinking about?

Commented [ND4R3]: Yeah, my initial thought was "no one knows intuitively what controlled exposure studies are, so why mention".... But if this is linked to or prompted by direct ref to NAS or Milloy.... Then controlled exposure makes sense. I am fine either way.

Commented [ST5]: Think we should link to this report, since it's online?

Commented [ND6R5]: I don't think I'd bother in this format. But here also, I am fine either way.

Commented [ST7]: ☹

Commented [ST8]: We can link to this, too. I think links are good: makes it look like we are not hiding anything (because we're not!)

As with many reports of this nature, the OIG also made recommendations for improvements and enhancements, primarily related to updating and clarifying EPA's internal policies and procedures. The report recognized the importance and efficacy of such high standards, and identified opportunities to strengthen our internal procedures even further. The EPA embraced the OIG's recommendations, including: (1) incorporating extra levels of feedback and review as study procedures are changed through the review process, (2) strengthening how we communicate internally, and (3) sharing even more information about potential exposure risks with study volunteers, even when these risks are minimal. In addition, many of the recommendations made by the OIG have been implemented agency-wide, even though they were directed solely at the work done in the Human Studies Facility.

Commented [ND9]: This last one gives me pause, as it suggests we weren't sharing enough and commits us to more. Did these 3 points come from "official" list, or are they our own summary of what we "embraced?"